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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,556	07/10/2001	Romano Deghenghi	87264-200	7188

28765 7590 03/31/2006

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/902,556

Applicant(s)

DEGHENGHI, ROMANO

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 19-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 and 28 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9, 19-25 and 29-41 is/are rejected.
- 7) ☒ Claim(s) 3 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-9 and 19-41 are pending.

The instant application which has been suspended due to potential interference is examined in this Office Action. Applicants' amendment filed May 6, 2003 is acknowledged. Applicants' response has been fully considered. Claims 1-4, 7-9 and 24-25 have been amended, and new claims 26-41 have been added. Therefore, claims 1-9 and 19-41 are examined.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 4-9, 19-25 and 29-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Bednarek (U.S. Patent 6,967,237, a 371 of PCT/US01/17026, filed May 25, 2001, which claims benefit of provisional application no. 60/207,920, filed May 30, 2000).

Bednarek teaches truncated ghrelin analogs have a formula of $Z^1\text{-GSXF}(Z)_n\text{-}Z^2$ or a pharmaceutical acceptable salt thereof, where X is a modified amino acid containing a bulky hydrophobic R group; Z is independently Leu, Ser, Pro, Glu or other amino acids; Z^1 is an optionally present protecting group for N-terminal group; Z^2 is an optionally present protecting group for C-terminal group; n is 0-19, since each Z is independently selected, the resulting $(Z)_n$

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can be a contiguous amino acid group present in ghrelin (e.g., human ghrelin, GSS(Octanoyl)FLSPEHQRVQQRKESKKPPAKLQPR; column 2, line 50-column 3, line 18; column 5, lines 5-44), thus compounds of $Z^1\text{-GSXF(Z)}_n\text{-Z}^2$ would include GSS(Octanoyl)FLSPE (claims 1, 2) and GSXF-NH₂ (compound 22; column 6, lines 59-65), where X is Ser(Octanoyl), compound 22 has the same structure as SEQ ID NO:1 of the instant application (claim 4). The reference also teaches a pharmaceutical formulation comprising an effective amount of the truncated ghrelin analog and a carrier, which can be prepared in a form (e.g., a solution or suspension, or tablets) suitable for administering by nasal, oral, inhalation or intravenous injection (columns 10, line 20-column 11, line 20; claims 5-9, 19-25, 29-41).

Claim Objections

3. Claims 3 and 26 are objected to because the claim depends from a rejected claim, claim 1.

Conclusion

4. Claims 1-2, 4-9, 19-25 and 29-41 are rejected; claims 3 and 26 are objected. Claims 27 and 28 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

February 21, 2006